

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NORTH CAROLINA  
STATESVILLE DIVISION

PATRICIA FAULISE, DEC., by and through )  
Personal Representative, JOE FAULISE, )  
husband, )

Plaintiffs, )

Case No. 5:05-CV-200-K

v. )

SMITHKLINE BEECHAM CORPORATION )  
d/b/a GLAXOSMITHKLINE, )

Defendants, )

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**STIPULATED PROTECTIVE ORDER OF CONFIDENTIALITY**

This is a product liability case involving Imitrex® (sumatriptan succinate), an FDA-approved prescription drug. To expedite the flow of discovery material; facilitate the prompt resolution of disputes over confidentiality; and adequately protect material entitled to be kept confidential, such as trade secrets, proprietary information, confidential research or development, and other confidential information and documents, **IT IS HEREBY STIPULATED** by plaintiff Patricia Faulise, by and through personal representative, Joe Faulise ("plaintiff") and defendant SmithKline Beecham Corporation (d/b/a GlaxoSmithKline) ("GSK"), pursuant to FED. R. CIV. P. 26(c), that the following provisions shall govern the documents, materials or other things or portions thereof (and the information contained therein) produced in discovery by any party to this litigation:

1. The following definitions shall apply to this Protective Order of Confidentiality (hereinafter "Order"):

a. "Party" shall mean a party to this action, any employee of such party, and any counsel for such party.

b. "Confidential information" shall mean all documents, materials, or other things, or portions thereof (and the information contained therein) that are designated by any party with the following:

CONFIDENTIAL. This document is subject to the Protective Order entered by the United States District Court for the Western District of North Carolina, Case No. 5:05-CV-200-K.

Deposition testimony and deposition exhibits produced during discovery in this case will automatically be deemed and treated as "confidential information." Interrogatory answers and responses to requests for production or for admission(s) in this case will automatically be deemed and treated as "confidential information." The term "documents, materials, or other things" shall include, but not be restricted to, all interrogatory answers, responses to requests for production or for admission(s), deposition testimony, and deposition exhibits and such items shall be deemed "confidential information" whether designated with the above-referenced protective legend or not.

c. "Receiving party" shall mean any party (including the party's counsel) or any consultant or other person to whom confidential information is furnished.

d. "Disclose" shall mean to reveal, provide, describe, make known or allow to be made known to any person confidential information.

e. "Person" shall mean any natural person or any business, legal, or governmental entity or association.

f. "Attorney" or "counsel" includes all members, partners, and employees of the attorney or counsel or law firm of which the attorney or counsel is a member, partner or employee.

g. "Healing arts practitioner" shall include medical doctors, pharmacists, nurses, chiropractors, osteopaths, psychologists, psychiatrists, therapists, counselors, hospitals, clinics, or any individual or institution that provides care, treatment, therapy, or counseling.

2. The following procedures shall apply to designated documents subject to this Order and disputes arising from such a designation:

a. Designation of documents as confidential shall be made by affixing to the document the following "Confidential Legend":

CONFIDENTIAL. This document is subject to the Protective Order entered by the United States District Court for the Western District of North Carolina, Case No. 5:05-CV-200-K.

The Confidential Legend shall be affixed to each page of material to be designated, but shall not obscure any part of the text. A designation shall subject the document, and its contents, to this Order without any further action on the part of the person desiring confidentiality. The inadvertent failure to stamp a document, or portion thereof, with the Confidential Legend in no way alters or waives the protected and confidential nature of the document and does not remove it from the scope of this Order. Further, all parties agree that they will not seek to use Confidential Information containing the Confidential Legend at trial, but will permit the producing party or its counsel to substitute clean copies for use only at trial to be returned to the producing party or its counsel thereafter.

b. Any party may designate any document, material, other thing, or portions thereof (and the information contained therein) as confidential.

c. If a party in good faith disagrees with a confidential designation made by the other party, said party shall inform counsel that made the confidential designation in writing of said disagreement within fifteen (15) days of said party's counsel's receipt of such a designation.

d. Upon written notification that a party disagrees with a confidential designation, counsel will confer in an effort to resolve the dispute without Court intervention.

e. If, after conferring, the parties cannot resolve the dispute, any party may move for a determination by the Court as to the appropriateness of the "confidential" designation.

f. Each document, material, or other thing, or portions thereof (and the information contained therein) designated as confidential shall retain that designation and shall remain subject to the terms of this Order until such time, if ever, that the Court renders a decision that a particular document, material, or other thing, or portions thereof (and the information contained therein) is not subject to this Order, and any and all proceedings or interlocutory appeals challenging such decision have been concluded.

3. The receiving party shall bear the cost of reproduction of all documents, materials, or other things, or portions thereof (and the information contained therein) which is stipulated to be twenty cents (\$.20) per page. This fee is intended and construed only as a reimbursement for reproduction. It does not indicate any transfer of ownership in the reproduced documents.

4. All confidential documents, materials, or other things, or portions thereof (and the information contained therein), including all deposition testimony of GSK witnesses,



shall be used only for the purposes of this case, including trial and preparation for trial, shall not be used for any other purpose, including other litigation (except as allowed by applicable rules of evidence), and shall not be disclosed to any person or governmental agency or otherwise made public except in compliance with the terms of this Order, or by determination of the Court. All documents, materials and other things, or portions thereof (and the information contained therein) including previous interrogatories, deposition testimony, documents produced in discovery (including audio and visual materials) produced during previous litigation by GSK shall be deemed confidential and not subject to challenge on that issue.

a. Except as otherwise provided herein, confidential information may be disclosed by the receiving party only to:

(1) any witness or potential witness for the purpose of conducting an examination of such witness during a trial or deposition or for the purpose of preparing such witness for the trial examination or deposition or interviewing such witness or potential witness, subject to the conditions set forth in paragraph 4(b), *infra*;

(2) the Court and any employee thereof; and

(3) any expert retained or consulted by a party for the purpose of obtaining such expert's advice or opinion regarding any issue in this litigation, but only to the extent necessary for the expert to provide such advice or opinion and subject to the conditions set forth in paragraph 4(b), *infra*.

b. Before disclosing a Confidential Document to any person (other than the Court), the requesting party shall give at least 10 days advance notice in writing to GSK, stating the names and addresses of the person(s) to whom the disclosure will be

made, identifying with particularity the documents to be disclosed, and stating the purposes of such disclosure. If, within the 10-day period, a motion is filed objecting to the proposed disclosure, disclosure is not permissible until and unless the Court denies such motion.

c. Before disclosing confidential information (other than to the Court), the receiving party shall ensure that the intended recipient of such disclosure has: (1) been provided a copy of this Order; and (2) executed an Agreement to Maintain Confidentiality in the form attached hereto as **Exhibit A**. Prior to such disclosure, the receiving party or its counsel shall prepare and maintain in a log the name, address, place of employment, and employment capacity of each such person who is to receive such information and shall maintain said log for five (5) years following termination of this action and exhaustion of all appeals relating thereto, together with a copy of the Agreement to Maintain Confidentiality executed by that person. Counsel for the receiving party agrees to notify the receiving party, other members of counsel's firm, and counsel's firm's regular employees of this Order and such persons' obligations to abide by the terms of such Order.

d. Any person to whom confidential information is disclosed by the receiving party or by any person who obtains such confidential information from the receiving party shall be bound by the provisions of this Order and is subject to all appropriate sanctions and remedies for any violation hereof.

e. If any confidential information is used or referred to in any pleading, motion, brief or other paper filed with the Court, such information shall be

marked with the confidential legend in accordance with paragraph 1(b), *supra*, and any such document shall be filed under seal with the following legend:

FILED UNDER SEAL in accordance with the Protective Order entered by the United States District Court for the Western District of North Carolina, Case No. 5:05-CV-200-K.

f. The receiving party will use reasonable efforts to limit the disclosure of confidential information to the minimum number of persons necessary to conduct this litigation and shall avoid unnecessary photocopying of such confidential information. If a receiving party makes a copy of any document, material, or other thing, or portions thereof (and the information contained therein) produced by any party, said copy shall have the protective legend in accordance with paragraph 1(b), *supra*.

g. Notwithstanding any other provisions of this Order, no documents, materials, or other things, or portions thereof (and the information contained therein) produced pursuant to this Order shall be disclosed to any employee or consultants of any other business entity engaged in the research, development, manufacturing, or distribution of any pharmaceutical, biologic, medical device, or other FDA-regulated product, or to any witness who is employed by such an entity or by any governmental agency, unless ordered by the Court.

5. GSK has the right to have persons, including security personnel, present in the inspection room at all times during plaintiff's inspection of documents, materials, or other things, or portions thereof (and the information contained therein) produced pursuant hereto. Plaintiff shall provide reasonable advance notice of the names of all individuals who will attend such inspections. The number of persons present during this process is limited to those necessary to adequately facilitate inspection and review of documents, and any such persons

must comply with the terms of this Order. The original documents, materials, or other things, or portions thereof (and the information contained therein) produced under the terms of this Order shall remain in the custody and control of the producing party at all times but may be inspected if questions arise from a review of copies of the originals.

6. All confidential information and copies of confidential information shall be returned and surrendered to the producing party or person upon the conclusion of this case. Conclusion shall be taken and construed as the date fifteen (15) days following the entry of a final, non-appealable order disposing of the case. Upon such conclusion, counsel of record for the receiving party shall notify counsel for the producing party of such return and surrender. Counsel for the receiving party shall make a reasonable effort to retrieve or request any document, material, or other thing, or portions thereof (and the information contained therein) or information subject to this Order from any party or non-party witness to whom such information has been given, and shall notify in writing counsel for the producing party of the failure to retrieve any such information, the reasons therefore, and the identity of the person from whom the document, material, or other thing, or portions thereof (and the information contained therein) or information could not be retrieved. Such notification shall identify any document, material, or other thing, or portions thereof (and the information contained therein) not returned.

7. This Order shall remain in full force and effect, and each person subject to this Order shall continue to be subject to the jurisdiction of this Court, for the purpose of enforcement of the terms of this Order, even after termination of the lawsuit. The Court shall not be divested of the power to enforce the terms of this Order as to any persons subject to the terms of this Order by the conclusion of this case, or by the filing of a notice of appeal or other



pleading that arguably has the effect of divesting this Court of jurisdiction of this matter generally.

8. All counsel shall at all times keep secure all notes, abstractions, or other work product derived from or containing confidential information, shall be obligated to maintain the confidentiality of such work product, and shall not disclose or reveal the contents of said notes, abstractions, or other work product after the documents, materials, or other things, or portions thereof (and the information contained therein) and information are returned and surrendered.

9. Nothing herein shall (a) prevent GSK from disclosing any document, material, or other thing, or portions thereof (and the information contained therein) that it has produced to any other person; or (b) otherwise restrict the use of such documents, materials, or other things, or portions thereof (and the information contained therein) by GSK. Such disclosure shall not be deemed to waive or otherwise modify the protection or confidentiality provided herein.

10. The parties shall negotiate in good faith prior to making any motion relating to any violation or alleged violation of this Order. Any party may expressly waive in writing the applicability of any provision of this Order to any information, document, material, or other thing, or portions thereof (and the information contained therein) that any party produces. Such waiver will apply only to the information, document, material, or other thing, or portions thereof (and the information contained therein) to which the applicability of any provision of this Order is expressly waived. A partial waiver as to certain information, document, material, or other thing, or portions thereof (and the information contained therein)

does not constitute a waiver as to the remainder of such information or document, material, thing, or other thing, or portions thereof (and the information contained therein).

11. Each person examining the produced materials or to whom any of the contents thereof are disseminated hereby agrees to be subject to the jurisdiction of this Court for appropriate proceedings in the event of any violation or alleged violation of this Order.

12. In order to protect against unauthorized disclosure of confidential or privileged information, GSK may redact from any Confidential Document any: (i) trade secrets or other highly confidential research, development or commercial information; (ii) names and any information that would identify clinical trial subjects or patients (other than Patricia Faulise) referred to in adverse reaction reports, product experience reports, consumer complaints and other similar data and any third party involved with such subjects or patients, including but not limited to, a physician or hospital or other institution; (iii) home addresses; (iv) DEA numbers of medical doctors; (v) personnel information not the specific focus of the request; and (vi) information about compounds and products that are not the subject of this litigation. Upon request for a specific document, GSK will identify the nature of information redacted in sufficient detail to allow plaintiff to determine whether a challenge to the redacted information may be appropriate. If the requesting party has a good-faith basis for challenging the redaction, counsel for the parties shall initially attempt to resolve the issue through discussions. If these discussions prove unsuccessful, counsel may move for a ruling, which may require this Court's *in camera* inspection of a document, on the issue of whether certain information is entitled to redaction. If the Court finds that said information should remain highly confidential, said information may not be used as evidence by either party at trial or at a hearing, and may not be relied upon by either party's retained or non-retained experts.


13. The parties recognize that when large volumes of documents are provided to the requesting party's counsel for preliminary inspection and designation for copying, these documents may not have yet been reviewed for confidentiality purposes, and GSK reserves the right to so designate documents after they are designated by the requesting party for copying. During the preliminary inspection process, all documents reviewed by the requesting party's counsel shall be treated as Confidential Documents.

14. Counsel for the receiving party shall make a good-faith effort to ensure compliance with the provisions of this Order. In the event of new counsel and/or a change in counsel, the parties and/or retiring counsel shall fully instruct new counsel of its responsibilities under this Order.

15. The parties hereto stipulate and consent to the issuance of this Order as an Order of this Court.

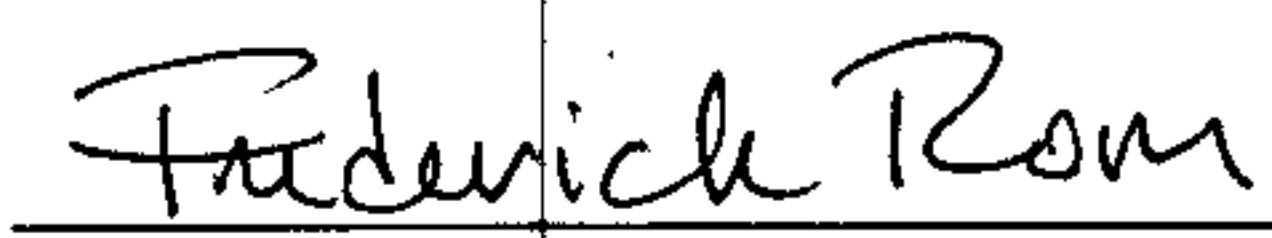
16. Any defendant who may be later added as a party or who may produce information pursuant to discovery on jurisdictional issues may rely and act upon this Order.

**STIPULATED AND AGREED TO BY:**

  
\_\_\_\_\_  
Richard J. Lutz  
LUTZEL GANDY & BROADWAY, PLLC  
542 Williamson Road  
Mooresville, North Carolina 28117

Date: 9/15/05

**Counsel for Plaintiff Patricia Faulise,  
by and through Personal Representative,  
Joe Faulise, Husband**

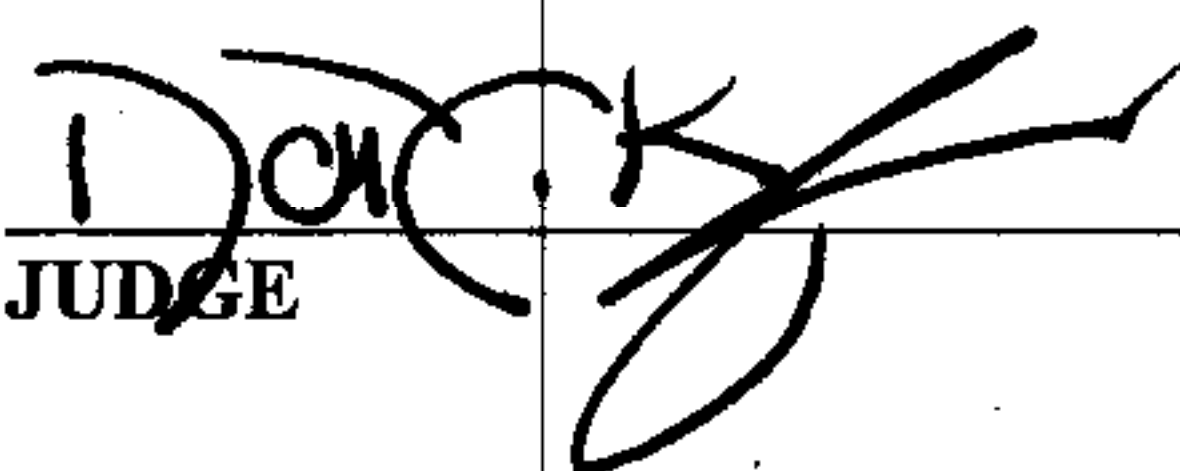
  
\_\_\_\_\_  
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Date: 9/15/05

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Kansas City, Missouri 64108

**Counsel for Defendant SmithKline Beecham  
Corporation d/b/a GlaxoSmithKline**

**IT IS SO ORDERED:**

  
\_\_\_\_\_  
JUDGE

Date: 9/15/05



Copies to:

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**ATTORNEYS FOR DEFENDANT  
SMITHKLINE BEECHAM CORPORATION  
(d/b/a GLAXOSMITHKLINE)**

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Defendants, )

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**EXHIBIT A**

**AGREEMENT TO MAINTAIN CONFIDENTIALITY**

The undersigned agrees:

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to a Protective Order in the above-captioned litigation; that I have been given a copy of and have read this Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Agreement to Maintain Confidentiality, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Protective Order.

I further agree that I shall not disclose to others, except in accordance with the Protective Order, any Confidential Documents as defined therein, or any information contained in such Confidential Documents, in any form whatsoever, and that such Confidential Documents and the information contained therein may be used only for the purposes authorized by the Protective Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Confidentiality Documents and information will continue even after this litigation concludes. I further agree that, if I fail to abide by terms of the Protective Order, I will be subject to the jurisdiction of this Court for the purpose of any proceedings relating to enforcement of the Protective Order.

Date: \_\_\_\_\_

By: \_\_\_\_\_

Subscribed and sworn to before me this \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.